DEC 2 1 2012

510(k) Summary of Safety and Effectiveness

Date Summary Prepared	October 26, 2012
Manufacturer/Distributor/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Christina Flores Regulatory Affairs Specialist Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1819 Fax: 239/598.5508 Email: Christina.flores@arthrex.com
Trade Name	Arthrex Pec Repair Button Arthrex Large Pec Button Arthrex Biceps Button Arthrex Proximal Biceps Button
Common Name	fastener, fixation, nondegradable, soft tissue
Product Code -Classification Name ***CFR***	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener MBI - fastener, fixation, nondegradable, soft tissue
Predicate Device	*K031666 - Arthrex FiberWire® Button Repair Kit* *K062747 - Arthrex RetroButton* *K083070 - Biomet ToggleLoc® System*
Purpose of Submission	This **Traditional 510(k)** premarket notification is submitted to obtain clearance for the Arthrex Pec Repair Button, Large Pec Button, Biceps Button and Proximal Biceps Button to expand the Arthrex Suture Button product offering. No prior submissions have been submitted for the subject devices.
Device Description and Intended Use	The four proposed Arthrex suture buttons are titanium oblong buttons that consist of two eyelets each that allow the buttons to be threaded with a variety of suture options. The ***Arthrex Pec Button, Large Pec Button, Biceps Repair Button and Proximal Biceps Buttons*** are used for fixation of bone to bone or soft tissue to bone, and are intended as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair in the knee, shoulder, and elbow and may include the following indications; anterior cruciate ligament, posterior cruciate ligament, pectoralis repair (minor/major), biceps tendon repair and reattachment

	(distal/proximal), acromioclavicular repair, and ulnar collateral ligament reconstruction.
Substantial Equivalence Summary	The proposed ***Arthrex Pec Button, Large Pec Button, Biceps Repair Button and Proximal Biceps Button*** are substantially equivalent to the predicate devices, in which the basic features and intended uses are the same. Cortical button fixation using a variety of button configurations and suture combinations has been shown to be a biomechanically strong method of treating various tendon and ligament injuries. The addition of Pectoralis repair (minor/major) to the indications of the proposed devices do not raise new questions of safety or effectiveness as the fixation properties of the proposed devices meet or exceed the ultimate load to failure seen clinically for this type of repair. Any other differences between the Arthrex proposed devices and the predicates are considered minor and do not raise questions concerning safety and effectiveness. Results of mechanical testing which included tensile strength, demonstrated that the proposed products met the acceptance criteria for the proposed indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Arthrex, Incorporated
% Ms. Christina Flores
Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, Florida 34108

December 21, 2012

Re: K123341
Trade/Device Name: Arthrex Pec Repair Button, Large Pec Button, Biceps Button and Proximal Biceps Button
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: October 26, 2012
Received: October 31, 2012

Dear Ms. Flores:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1 Indications for Use Form

Indications for Use

510(k) Number: K123341

Device Name: Arthrex Pec Repair Button, Large Pec Button, Biceps Button, and Proximal Biceps Button

Indications for Use:

The ***Arthrex Pec Repair Button, Large Pec Button, Biceps Button, and Proximal Biceps Button*** are used for fixation of bone to bone or soft tissue to bone, and are intended as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair in the knee, shoulder, and elbow and may include the following indications; anterior cruciate ligament, posterior cruciate ligament, pectoralis repair (minor/major), biceps tendon repair and reattachment (distal/proximal), acromioclavicular repair, and ulnar collateral ligament reconstruction.

Prescription Use _X_ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey Hanley

For Division of Orthopaedic Devices